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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/848,806
Filing Date: May 04, 2001
Appellant(s): SHEEN, JEN

James D. DeCamp
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed January 3, 2005.

A statement identifying the real party in interest is contained in the brief.

*(1) Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

*(2) Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

*(3) Status of Claims*

The statement of the status of the claims contained in the brief is correct.

*(4) Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

*(5) Summary of Invention*

The summary of invention contained in the brief is correct.

*(6) Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

The rejection of claims 1-8, 10-16 and 54-57 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is withdrawn.

The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "consists essentially of", is withdrawn.

The rejection of claims 1-8, 10-16 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lusso et al. (WO 99/02655, published 21 January 1999) in view of Urao et al. (SPTREMBL Accession No. Q39016, 01 November 1996, Calcium-dependent protein kinase ATCDPK2 from *Arabidopsis thaliana*), is withdrawn.

***(7) Grouping of Claims***

The rejection of claims 1-8, 10-16 and 54-57 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

***(8) Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

***(9) Prior Art of Record***

LEE J.Y. et al. Kinetic and calcium-binding properties of three calcium-dependent protein kinase isoenzymes from soybean. Biochemistry, May 12, 1998, Vol. 37, No. 19, pages 6801-6809.

LINTHORST et al. Constitutive expression of pathogenesis-related proteins PR-1, GRP, and PR-S in tobacco has no effect on virus infection. The Plant Cell, March 1989, Vol. 1, No. 3, pages 285-291.

LUSSO et al. WO 99/02655, published 21 January 1999.

SHEEN, WO 98/26045, published 18 June 1998.

URAO et al. SPTREMBL Accession No. Q39016, 01 November 1996, Calcium-dependent protein kinase ATCDPK2 from *Arabidopsis thaliana*.

*(10) Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-7, 10-16, 54 and 56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is set forth in the Office Actions mailed April 10, 2003 and December 24, 2003, and is repeated below.

Claims 1-8, 10-16 and 54-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheen (WO 98/26045, published 18 June 1998). This rejection is set forth in the Office Actions mailed April 10, 2003 and December 24, 2003, and is repeated below.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 10-16, 54 and 56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of producing a plant having increased resistance to any disease causing pathogen, including a plant pathogen, by regenerating a plant from a plant cell that overexpresses a nucleic acid molecule that encodes a calcium-dependent protein kinase

polypeptide, said nucleic acid molecule being selected from the group consisting of (i) a nucleic acid molecule encoding a polypeptide of SEO ID NO:1, and (ii) a nucleic acid molecule encoding a polypeptide having at least 80% identity to the polypeptide of SEO ID NO:1.

Nucleic acid molecules encoding a polypeptide of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1 whose overexpression in a plant increases the level of resistance to a disease-causing pathogen are not described. While claim 1 is limited to sequences having a specific structure or having a specific amount of similarity thereto, the specification does not describe a representative number of species falling within the scope of the claimed genus. The specification indicates only that a plant having increased disease resistance may be produced by overexpressing a calcium-dependent protein kinase polypeptide such as CDPK2 (SEQ ID NO:2) or CDPK4 (SEQ ID NO:4) or polypeptides that consist essentially of the protein kinase domain of a CDPK or CDPKs that are orthologs of *Arabidopsis* CDPKs (page 2 lines 1-21; page 11 lines 17-21), but such plants are not described. Accordingly, the specification does not describe the specific structural features of nucleic acid molecules encoding a polypeptide having at least 80% identity to SEQ ID NO:1 that are correlated with the function of increasing the level of resistance to a disease-causing pathogen upon overexpression in a plant, or that are correlated with calcium dependent protein kinase activity.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that

"naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-16 and 54-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheen (WO 98/26045, published 18 June 1998).

The claims are drawn to a method of producing a plant having increased disease resistance, including resistance to disease caused by plant pathogens, by regenerating a plant

from a plant cell, including a monocotyledonous or dicotyledonous cruciferous plant cell and including transgenic plant cells, that ectopically overexpress a nucleic acid molecule that encodes a calcium-dependent protein kinase (CDPK) polypeptide, said nucleic acid molecule being selected from the group consisting of (i) a nucleic acid molecule encoding a polypeptide of SEO ID NO:1, and (ii) a nucleic acid molecule encoding a polypeptide having at least 80% identity to the polypeptide of SEO ID NO:1, including a CDPK polypeptide that consists essentially of a protein kinase domain or a constitutively active CDPK, and a CDPK derived from *Arabidopsis* or an ortholog thereof, under the control of an inducible, constitutive or tissue-specific promoter.

Sheen teaches a method of producing a plant having increased environmental stress resistance (page 2 line 16 to page 5 line 8; page 23 line 21 to page 35 line 12) by regenerating a plant from a plant cell, including a monocotyledonous (page 12, maize for example) or dicotyledonous cruciferous plant cell (page 8 line 23, for example) and including transgenic plant cells, that overexpress a nucleic acid encoding a CDPK of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1, including a CDPK polypeptide that consists essentially of a protein kinase domain (page 3 line 3 for example), and ATCDPK1 or ATCDPK1a (derived from *Arabidopsis*, page 16), under the control of an inducible, constitutive or tissue-specific promoter (page 26 line16 to page 27 line 27). While Sheen does not explicitly teach that the disclosed method increases disease resistance, such an effect would be inherent to the method taught by Sheen, as the claimed method requires only the overexpression of a nucleic acid molecule encoding a calcium-dependent protein kinase polypeptide in a plant, which is taught by Sheen. Furthermore, while Sheen does not explicitly teach the use of a constitutively active CDPK, the

CDPK taught by Sheen is presumed to be constitutively active, as the method taught by Sheen does not require an additional step to activate the CDPK, and as a constitutive promoter is used. Sheen also teaches ectopic expression in that Sheen teaches the use of a constitutive promoter (CaMV 35S) for expression, which would necessarily lead to ectopic expression (page 27 lines 15-27).

*(11) Response to Argument*

*Claim Rejections - 35 USC § 112*

In response to the rejection of 1-7, 10-16, 54 and 56 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, Appellant points out that because SEQ ID NO: 1 is presented in Appellant's specification, there can be no question that the written description requirement is satisfied with respect to a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1 (brief page 5).

Appellant's disclosure of a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1 is acknowledged, but the Examiner maintains that none of the rejected claims are limited to the use of a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1.

In response to the Office's assertion that the specification does not describe the specific structural features that are correlated with the function of increasing the level of resistance to a disease-causing pathogen, Appellant notes that the sequences used in the claimed methods

encode calcium dependent protein kinase (CDPK) polypeptides, and such calcium dependent protein kinase activity is clearly a functional limitation that distinguishes polypeptides used in the methods from other polypeptides. Appellant also notes that polypeptides used in the claimed methods are distinguished from other polypeptides by both the structural characteristic of having at least 80% sequence identity to SEQ ID NO:1 and by the specific functional characteristic of having calcium dependent protein kinase activity. Appellant maintains that the rejection should be reversed as clear distinguishing characteristics that are shared by the claimed proteins are disclosed in Appellant's specification. (brief pages 5-6)

The Examiner maintains that the specification does not describe the specific structural features of SEQ ID NO:1 that are correlated with its function of increasing the level of resistance to a disease-causing pathogen, or with its calcium dependent protein kinase activity, such that one skilled in the art could distinguish those nucleic acid molecules that encode a polypeptide having at least 80% identity to SEQ ID NO:1 that increases the level of resistance to a disease-causing pathogen and exhibits calcium dependent protein kinase activity (the claimed invention) from those nucleic acid molecules that encode a polypeptide having at least 80% identity to SEQ ID NO:1 that do NOT increase the level of resistance to a disease-causing pathogen or exhibit calcium dependent protein kinase activity (other materials). Merely saying that the nucleic acid molecules encode a polypeptide having at least 80% identity to SEQ ID NO:1 that increases the level of resistance to a disease-causing pathogen and exhibits calcium dependent protein kinase activity does not describe the structure of such molecules. See *University of California v. Eli Lilly,* 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997), where it states:

> naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have

> previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. *See Fiers,* 984 F.2d at 1171, 25 USPQ2d at 1606.

Further, the specification does not describe a representative number of species falling within the scope of the claimed genus, such that one skilled in the art could distinguish those nucleic acid molecules that encode a polypeptide having at least 80% identity to SEQ ID NO:1 that increases the level of resistance to a disease-causing pathogen and exhibits calcium dependent protein kinase activity (the claimed invention) from those nucleic acid molecules that encode a polypeptide having at least 80% identity to SEQ ID NO:1 that do NOT increase the level of resistance to a disease-causing pathogen or exhibit calcium dependent protein kinase activity (other materials). The specification indicates only that a plant having increased disease resistance may be produced by overexpressing a calcium-dependent protein kinase polypeptide such as CDPK2 (SEQ ID NO:2) or CDPK4 (SEQ ID NO:4) or polypeptides that consist essentially of the protein kinase domain of a CDPK or CDPKs that are orthologs of *Arabidopsis* CDPKs (page 2 lines 1-21; page 11 lines 17-21). The Examiner maintains that the two disclosed nucleotide sequences, CDPK2 (SEQ ID NO:2) and CDPK4 (SEQ ID NO:4), which encode polypeptides having 95% and 100% identity to SEQ ID NO:1 and which were obtained from the same species of organism (the plant *Arabidopsis thaliana*), are not representative of the genus of sequences recited in the rejected claims, i.e. sequences which may be obtained from any species of organism and which encode polypeptides having at least 80% identity to SEQ ID NO:1 and which function to increase the level of resistance to a disease-causing pathogen or that exhibit calcium dependent protein kinase activity.

***Claim Rejections - 35 USC § 102***

In response to the rejection of claims 1-8, 10-16 and 54-57 under 35 U.S.C. 102(b) as being anticipated by Sheen (WO 98/26045, published 18 June 1998), Appellant points out that the rejected claims require "regenerating a plant from said plant cell, wherein said CDPK polypeptide is expressed in said plant, increasing the level of resistance to a disease-causing pathogen as compared to a naturally-occurring plant", and notes that while WO 98/26045 teaches the discovery of using a CDPK to protect a plant against stresses such as drought, salinity, cold, and heat, WO 98/26045 is nonetheless silent on whether CDPK regulates disease resistance genes. Appellant maintains that there is no evidence indicating that disease resistance is necessarily present, and that contrary to the Office's assertion that "no positive method steps that would distinguish the claimed method from the method disclosed in the prior art", the claims require "increasing the level of resistance to a disease-causing pathogen as compared to a naturally-occurring plant", which WO 98/26045 does not teach. (brief page 10)

The rejection is maintained because WO 98/26045 teaches the same method as set forth in the rejected claims, namely a) providing a plant cell overexpressing a nucleic acid encoding a CDPK of SEQ ID NO:1 or having at least 80% identity to SEQ ID NO:1, and b) regenerating a plant, wherein the CDPK polypeptide is expressed in said plant. Further, the limitation "increasing the level of resistance to a disease-causing pathogen as compared to a naturally-occurring plant" recited in claim 1 is not recited as a positive method step; it is recited as an inherent consequence of the expression of the CDPK polypeptide in the plant, as step b) of the method requires "regenerating a plant from said plant cell, wherein said CDPK polypeptide is

expressed in said plant, increasing the level of resistance to a disease-causing pathogen as compared to a naturally-occurring plant.". Because expression of the CDPK polypeptide in the plant inherently increases the plant's level of resistance to a disease-causing pathogen, WO 98/26045 need not teach whether CDPK regulates disease resistance genes in order to anticipate the rejected claims.

See *Integra Life Sciences I Ltd. v. Merck KGaA,* 50 USPQ2d 1846 (DC SCalif, 1999) which teaches that a reference teaching a process may anticipate claims drawn to a method comprising the same process steps, despite the recitation of a different intended use in the preamble or the later discovery of a particular property of one of the starting materials or end products.

See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993), which teaches that a reference teaching a claimed process, wherein one of the claimed properties of a product used in the prior art process is inherent but undisclosed by the reference, may be properly applied as art against the claimed process.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Cynthia Collins
Examiner
Art Unit 1638

Cynthia Collins 3/10/05

CC
March 10, 2005

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